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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/675,852

09/30/2003

Jacqueline E. Heard

MBI-0022CIP

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04/14/2008

MENDEL BIOTECHNOLOGY C/O MOFO SF
425 MARKET STREET
SAN FRANCISCO, CA 94105

EXAMINER

KRUSE, DAVID H

ART UNIT

PAPER NUMBER

1638

MAIL DATE

DELIVERY MODE

04/14/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/675,852	Applicant(s) HEARD ET AL.	
	Examiner David H. Kruse	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 10-13, 15 and 36-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 10-13, 15 and 36-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 January 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

STATUS OF THE APPLICATION

1. This Office action is in response to the Amendment and Remarks filed on 18 September 2007.
2. The drawings filed 21 January 2008 are approved by the Examiner, and the amendment to the specification filed 21 January 2008 has obviated the objection to the specification under the Sequence Rules.
3. The Examiner also notes that Applicants have deleted the New Matter introduced into the specification by a corrective amendment on 18 September 2007.
4. Those objections or rejections not specifically addressed in this Office action are withdrawn in view of Applicants' amendments.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

6. Applicants argue that support for both SEQ ID NO: 3 and hybridization language may be found in the present application, and also in priority applications 60/125,814, filed March 23, 1999 (e.g., sequence "G482" in "Family 13. CAAT Binding Protein...", and on page 47, lines 1-2 and page 63, lines 25-31), and 60/166,228, filed November 17, 1999 (e.g., see the pages for "Summary of Overexpressor G482, Family CAAT", and page 20, lines 10-11). Applicants argue that the former application teaches how to prepare transgenic plants, and the latter application discloses osmotic stress-tolerant transgenic plants overexpressing G481 (present SEQ ID NO: 2) and salt-tolerant transgenic plants overexpressing G482 (presently SEQ ID NO: 4) (pages 8-9 of the

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Remarks). The Examiner could not find the asserted support on the cited pages of priority application 60/125,814. While the Examiner could find support for the invention of claims 4, 6, 37 and 38 in priority application 60/166,228, filed November 17, 1999, the Examiner could not find adequate support under 35 U.S.C. § 112, first paragraph for the remaining claims in said application.

Consequently, for claims 1-3, 5, 10-13, 15 and 36 Applicants are afforded the priority of 30 September 2003 for the purposes of applying the prior art.

Claim Rejections - 35 USC § 112

7. Claims 1-3, 5, 10-13 and 15 remain rejected and claim 36 is rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 11 April 2007. Applicant's arguments filed 18 September 2007 have been fully considered but they are not persuasive.

Applicants argue that as shown in Table 6 on page 95 of the present application, *Arabidopsis* sequences G482, G481, G485 and rice sequence G3395 (SEQ ID NOs: 2, 4, 6 and 74, respectively) each have the ability to confer increased tolerance to at least some of various abiotic stresses, including heat, drought, salt, sugar, ABA and cold. G481 and G3395 both have conserved B domains that are 83% identical to the similar domain of G482. Applicants argue that G485 has a B domain with an intermediate

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identity, 94%, to the G482 domain (see Table 1 beginning on page 31). Applicants argue that the specification describes two nucleotide sequences that encode polypeptides having conserved domains with at least 83% sequence identity to the conserved domain of amino acid coordinates 26-116 of SEQ ID NO: 4, and, furthermore, these sequences function in transgenic plants as claimed (page 10 of the Remarks). These arguments are not found to be persuasive. The function "confers increased abiotic stress tolerance" is not a specific function. The evidence in Table 6 shows that the G482 polypeptide confers heat tolerance when overexpressed in a plant, whereas the G481 polypeptide does not but does confer drought tolerance. The G485 and G3395 polypeptides do not confer either heat tolerance or drought tolerance to a transgenic plant but tolerance to high salt. In addition, the type of tolerance conferred by the G481 polypeptide appears to be relative to the promoter used. Hence, the conservation of structure is not necessarily an indication for conservation of function in the instant case.

Applicants argue that the specification also provides methods for identifying orthologs and homologs using percentage identity and hybridization methods, both well recognized arts. Applicants argue that "[t]he transcription factors of the present invention each possess a B or conserved domain, including the orthologs of G482 found by BLAST analysis, as described below" (page 33, lines 1-2). Applicants argue that hybridization conditions provided in the specification are also note above in support of the claims amendments. Applicants argue that G3395, for example, is a sequence found in a sequence database, determined to be similar to G482 and its function

paralogs, and successfully tested in plants (page 10 of the Remarks). This argument is not found to be persuasive for the reasons given above.

The Examiner acknowledges antecedent bases in the specification for the limitations in claims 2 and 3 (page 11, 1st paragraph of the Remarks).

Applicants argue that they did indeed provide "a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus". Applicants argue that the list of conserved B domains found in Table 1 beginning at page 31. Applicants argue that the Lilly court set out exemplary ways in which a genus of cDNAs could be described: "[a] description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, *defined by nucleotide sequence*, falling within the scope of the genus", 296 F.3d, 63 USPQ2d, *emphasis added*. Applicants argue that the number of functional sequences described represent a practical sampling of a considerable number of sequence species.

Applicants argue that between the eudicots soy and *Arabidopsis*, and the monocot rice, are a very large number of plant species and their related sequences. Applicants argue that there are about 170,000 eudicot plant species that can produce G482 homologs evolutionarily more closely related to SEQ ID NOs: 3-4 than to the rice G3395 ortholog. Applicants argue that these functionally related sequences found in very diverse plant species strongly suggest that a considerable majority, if not all or almost all, of the plant species between *Arabidopsis* and rice will have conserved G482 homolog structure and associated function. Applicants argue that to suggest otherwise would be to suggest that very similar sequences in distantly related plant species exist because of mere

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coincidence and not the evolutionary imperative to retain sequence structure and function. Applicants argue that many orthologous monocot-derived sequences (there are about 65,000 monocot species) should also retain similar functions; it seems unlikely that rice, the first species examined and found to have a structurally and functionally related sequence, is the only monocot plant to have retained functional an orthologous G482 clade transcription factor after 130 to 240 million years of evolution (the generally accepted span from the monocot-eudicot divergence) (page 11 of the Remarks). These arguments are not found to be persuasive for the reasons given above. In addition Table 1 of the instant specification recites a number of polypeptide encoding polynucleotides that would fall within the claimed genus but Applicants provide no evidence that all of these species confer abiotic stress tolerance in a transgenic plant.

Applicants argue that the Office action contends that the da Costa e Silva reference confirms "a method of producing transgenic plants tolerant to [water deprivation]. Applicants argue that the sequences used by da Costa e Silva were derived from a moss, a very primitive plant and distant (from *Arabidopsis* or flee) plant. Applicants argue that the Examiner's assertion would seem to support the definitive conservation of structure and function and the very high likelihood of finding with routine experimentation numerous sequences from very diverse species that function as claimed. Applicants argue that the skilled artisan would understand that a very large number of sequences encompassed by the claims can be readily found in plant species that lie in intermediate positions on the evolutionary tree, and would recognize that

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Applicants argue that they have described and were in possession of many examples of functional species each *comprising partial structures coupled with a disclosed correlation between function and structure* (Enzo, *supra*) common to members of the genus (page 12, 1st and 2nd paragraphs of the Remarks). These arguments are not found to be persuasive. Da Costa e Silva actually state that “the cellular processes leading to drought, cold and salt tolerance in model, drought- and/or salt-tolerant plants are complex in nature and involve multiple mechanisms of cellular adaptation and numerous metabolic pathways” (column 1, lines 49-53). Da Costa e Silva also states that “Although it is generally assumed that stress-induced proteins have a role in tolerance, direct evidence is still lacking, and the function of many stress-responsive genes are unknown” (column 2, lines 27-31). Hence, at the time of the invention of Da Costa e Silva, one of skill in the instant art would not assume the function of a transcription factor based on it’s structural features, but would in fact deem empiric evidence of specific function as required.

Applicants argue that rather than claiming “highly stringent hybridization conditions”, instant claim 1 spells out precise hybridization conditions that are likely to be more stringent (1X SSC at 60 C vs. 6X SSC at 65 C) than those found in Example 9 of the Guidelines. Applicants argue that in contrast to Example 9 (of the Guidelines), four, rather than one, functional species are disclosed, and numerous putative orthologs are provided (see, for example, Figures 6A-6F) (paragraph spanning pages 12-13 of the Remarks). This argument is not found to be persuasive for the reasons given above.

Given the teachings of Da Costa e Silva, one skilled in the art would not have deemed Applicants in possession of the invention as broadly claimed.

8. Claims 1-3, 5, 10-13 and 15 remain rejected and claim 36 is rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method of making and a transgenic plant made, comprising a recombinant polynucleotide encoding a polypeptide of SEQ ID NO: 4 that exhibits increased germination when grown on high salt or mannitol containing medium and increased heat tolerance, does not reasonably provide enablement for methods of making and transgenic plants made comprising other recombinant polynucleotides or for methods of making transgenic plants exhibiting other phenotypic characteristics. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is repeated for the reason of record as set forth in the last Office action mailed 11 April 2007. Applicant's arguments filed 18 September 2007 have been fully considered but they are not persuasive.

Applicants argue that Table 6, in fact, does not necessarily show varying phenotypes, but does show phenotypes that were observed with a limited number of lines that were generated to support the claims. Applicants argue that absence of a positive result thus does not mean that the sequence fails to provide the trait, but merely that the trait has not been observed thus far. Applicants argue that for example, G481 did confer hyperosmotic stress tolerance, as shown in priority application 60/166,228, which is a strong indication that the sequence will also confer drought tolerance,

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another form of hyperosmotic stress. Applicants argue that subsequent experiments with a greater number of transgenic plant lines have shown that G481 does confer drought tolerance in plants. See, for example, priority US patent application 10/374,780, Table 4 on page 67: "[SEQ ID NO:] 87 ...G481 ..OE [overexpressor] ...Drought...Increased tolerance to drought". Applicants argue that they believe that many sequences that fall within the scope of the claims, for example, sequences listed in Table 1, will function as claimed by conferring increased tolerance to water deprivation, salt, cold, etc (page 13 of the Remarks). These arguments are not found to be persuasive. Given the vast number of variants that would fall within the claimed genus, it would have required undue trial and error experimentation by one of skill in the art at the time of Applicants' invention to make and use the transgenic plants as broadly claimed.

Applicants argue that Table 6 on page 95 discloses that *Arabidopsis* sequences G482, G481, G485 and rice sequence G3395 (SEQ ID NOs: 2, 4, 6 and 74, respectively) each have the ability to confer increased tolerance to at least some of various abiotic stresses, including heat, drought, salt, sugar, ABA and cold. Applicants argue that G481 and G3395 both have conserved B domains that are 83% identical to the similar domain of G482. Applicants argue that G485 has a B domain with an intermediate identity (94%) to the G482 domain (see Table 1 beginning on page 31). Applicants argue that the specification does indeed describe nucleotide sequences encoding a genus of polypeptides having a conserved domain with at least 83% sequence identity to the conserved domain of amino acid coordinates 26-116 of SEQ ID

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NO:4, and, furthermore, these sequences function in transgenic plants as claimed (paragraph spanning pages 13-14 of the Remarks). These arguments are not found to be persuasive. The instant specification states that "manipulating transcription factor levels in a plant offers tremendous potential in agricultural biotechnology for modifying a plant's traits, including traits that improve a plant's survival and yield during periods of abiotic stress, including germination in cold and hot conditions, and osmotic stress, including drought, salt stress, and other abiotic stresses, as noted below" (page 2, lines 22-26 of the specification). Hence, the breadth of "abiotic stress" tolerances encompassed by the instant claims is vast as well as relative to the plant being transformed.

Applicants argue that Table 1 of the specification also provides numerous sequences that are homologous to SEQ ID NO: 3-4 and below Table 1 it is disclosed that "[t]he transcription factors of the present invention each possess a B or conserved domain, including the orthologs of G482 found by BLAST analysis, as described below. Applicants argue that the B domain of the transcription factors will bind to a transcription-regulating region comprising the motif CCAAT" (page 32, lines 1-5, emphasis added) "Orthologs and paralogs are evolutionarily related genes that have similar sequence and similar functions" (page 37, lines 7-8, emphasis added). Applicants argue that Table 1 thus includes prophetic examples ("[a]n example may be 'working' or 'prophetic' ", MPEP 2164.02"). Applicants argue that the specification also provides methods for identifying orthologs and homologs using percentage identity and hybridization methods, both well recognized arts. Applicants argue that "[t]he

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transcription factors of the present invention each possess a B or conserved domain, including the orthologs of G482 found by BLAST analysis, as described below" (page 33, lines 1-2). Applicants argue that hybridization conditions provided in the specification are also note above in support of the claims amendments. Applicants argue that G3395, for example, is a sequence found in a sequence database, determined to be similar to G482 and its function paralogs, and successfully tested in plants (page 14, 2nd and 3rd paragraph of the Remarks). These arguments are not found to be persuasive. See *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970) which teaches "That paragraph (35 USC 112, first) requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved."

Applicants argue that they have shown that sequences homologous to SEQ ID NOs: 3 and 4 from very diverse species predictably confer the phenotype of increased tolerance to numerous abiotic stresses (e.g., as noted in Table 6). Applicants argue that regarding the Wands factors, Applicants wish to note that it would not require undue experimentation to find sequences that are closely-related to G482 using BLAST or

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hybridization analysis, test them in plants, and identify those sequences that confer increased tolerance to the claimed abiotic stresses. Applicants argue that since sequences from both dicots and monocots confer increased abiotic stress, the likelihood of finding other operative species is high since conservation of structure and function has been conserved over many millions of years and in thousands of plant species. Applicants argue that the da Costa e Silva reference cited in the Office action which allegedly confirms "a method of producing transgenic plants tolerant to [water deprivation]. Applicants argue that the sequences used by da Costa e Silva were derived from a moss. Applicants argue that the Office action seems to support the high conservation of structure and function and the very high likelihood of finding, with routine experimentation, numerous sequences from very diverse species that function as claimed (page 14, last paragraph of the Remarks). These arguments are not found to be persuasive for the reasons given above. Da Costa e Silva actually state that "the cellular processes leading to drought, cold and salt tolerance in model, drought- and/or salt-tolerant plants are complex in nature and involve multiple mechanisms of cellular adaptation and numerous metabolic pathways" (column 1, lines 49-53). Da Costa e Silva also states that "Although it is generally assumed that stress-induced proteins have a role in tolerance, direct evidence is still lacking, and the function of many stress-responsive genes are unknown" (column 2, lines 27-31). Hence, at the time of the invention of Da Costa e Silva, one of skill in the instant art would not assume the function of a transcription factor based on it's structural features, but would in fact deem empiric evidence of specific function as required.

Applicants argue that they are unsure how the Smolen reference relates to the present claims. Applicants argue that the fact that some changes in functional residues in any protein can produce unpredictable results is not at issue. Applicants argue that the present claims require the functions of increased abiotic stress tolerance. Applicants argue that while it may be possible to create a non-functional species of practically any invention (e.g., proteins can be denatured or physically isolated from their targets), the possible existence of non-functional species is not at issue; "[w]ithout undue experimentation or effort or expense the combinations which do not work will readily be discovered and, of course, nobody will use them and the claims do not cover them" (page 15 of the Remarks). The issue of undue trial and error experimentation in the instant case is directly related to the breadth of the claimed invention, and the unpredictability in the instant art at the time of Applicants' invention.

Applicants argue that Claim 1 comprises the claim element "abiotic stress tolerance ... selected from the group consisting of increased tolerance to cold, increased tolerance to salt, increased tolerance to mannitol, and increased tolerance to water deprivation." Applicants argue that Claim 12 comprises the claim element "abiotic stress ... selected from the group consisting cold, salt, mannitol, and water deprivation". Applicants argue that there is thus very specific guidance with respect to which types of environmental stress tolerance would be conferred to plants that express the plant transcription factor coding sequences recited in the claims. Applicants argue that the Office action does not state why testing transgenic plants comprising plant transcription factor coding sequences under a variety of different conditions would constitute a trial

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and error approach. Applicants argue that this approach is exactly the sort of routine experimentation in which Applicants engage, and it is apparently the sort of approach, according to the Office action, engaged in by da Costa e Silva. Applicants argue that since very diverse plant species have retained very similar sequences that confer the function of increasing tolerance to the claimed abiotic stresses, it is a matter of routine to find functional sequences from the numerous plants that fall, for example, between eudicots and monocots, or, according to the Office action, between eudicots and mosses (page 16 of the Remarks). These arguments are not found to be persuasive for the reasons given above. The teachings of da Costa e Silva have been addressed above as well.

Claim Rejections - 35 USC § 102

9. Claims 1-3, 5, 6, 10-13 and 15 remain rejected and claim 36 is rejected under 35 U.S.C. § 102(e) as being anticipated by da Costa e Silva *et al* (U.S. Patent 6,677,504, filed 6 April 2001 and claiming benefit of U.S. Provisional Application 60/196,001 filed 7 April 2000) taken with the evidence of Fourgoux-Nicol *et al* (1999, Plant Molecular Biology 40: 857-872). This rejection is repeated for the reason of record as set forth in the last Office action mailed 11 April 2007. Applicant's arguments filed 18 September 2007 have been fully considered but they are not persuasive.

Applicants argue that independent claims 1 and 12 have been amended such that the recombinant polynucleotide comprised within the transgenic plants of the invention specifically hybridizes to the complement of the sequence set forth in SEQ ID NO: 3 under stringent conditions comprising two wash steps of 1x SSC, 1% SDS at 60°C

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for 45-60 minutes for each wash step. SEQ ID NO: 3 and this hybridization language may be found in priority application 60/166,228, filed November 17, 1999 (e.g., see the pages for "Summary of Overexpressor G482, Family CAAT", and page 20, lines 10-11). Applicants argue that Application 60/166,228 teaches how to prepare transgenic plants, and discloses osmotic stress-tolerant transgenic plants overexpressing G481 (present SEQ ID NO: 2) and salt-tolerant transgenic plants overexpressing G482 (presently SEQ ID NO: 4). Applicants argue that Application 60/125,814, filed March 23, 1999 discloses sequence "G482" in "Family 13. CAAT Binding Protein...", and hybridization methods and conditions on, for example, page 47, lines 1-2 and page 63, lines 25-31. Applicants argue that these and subsequent priority applications disclose the present sequences, transgenic plants, and methods for determining abiotic stress tolerance. Applicants argue that both of these applications were filed before the priority date of USPN 6,677,504, and priority application 60/125,814 was filed prior to the Fourgoux-Nicol et al reference which was "taken with the evidence of" USPN 6,677,504 for the purposes of establishing a rejection under 35 U.S.C. § 102(e) (page 17 of the Remarks). The issue of priority for the instant claims has been addressed above under Item 6 of the instant Office action. This rejection is maintained for the reasons of record.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1-6, 10-13, 15 and 36-38 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Edwards *et al* (July 1998, Plant Physiology 117: 1015-1022) in view of Harada *et al* (U.S. Patent 6,235,975 B1, filed 24 June 1998).

Edwards teaches a recombinant polynucleotide encoding the AtHAP3b CAAT-box transcription factor having 874 nucleotides identical to that of Applicant's SEQ ID NO: 3, encoding 188 of 190 amino acids of Applicant's SEQ ID NO: 2. The AtHAP3b CAAT-box transcription factor taught by Edwards as the "conserved domain" of Applicants' SEQ ID NO: 4. Edwards teaches that expression of the AtHAP3b CAAT-box transcription factor in leaves from plants grown in soil but not in those from liquid culture may suggest environmental regulation of this gene, perhaps in relation to osmotic stress (page 1021, left column, 2nd paragraph). Edwards teaches that further research is required to understand the regulation of this factor and its role in developmental and environmental responses.

Edwards does not specifically teach a transgenic plant comprising said recombinant polynucleotide.

Harada teaches that at the time of Applicant's invention, it was obvious to transform plants with recombinant polynucleotides encoding CAAT-box transcription factors. Harada teaches a transgenic plant comprising a recombinant nucleotide sequence encoding a LEC1 polypeptide that comprises a CCAAT binding factor domain. Harada teaches that said recombinant nucleotide sequence can be operably linked to a constitutive promoter (claim 7), an inducible promoter (claim 9) or a tissue-specific promoter (claim 11). Harada teaches a method of transforming a plant by

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selecting a polynucleotide, inserting into an expression vector, introducing said vector into a plant or plant cell and selecting a transformed plant (see column 13, lines 49-58; columns 15-17; and column 20, last paragraph to column 21). Harada teaches that the transgenic plant can be a dicot, a monocot or a gymnosperm (column 21, lines 31-45).

The claims would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention, because it would have been obvious to isolate a polynucleotide encoding the complete AtHAP3B gene and transform a plant with the AtHAP3b CAAT-box transcription factor taught by Edwards. The invention as a whole is directed to a transgenic plant. The characteristic of abiotic stress tolerance would have naturally flown from the use of the AtHAP3b CAAT-box transcription factor to transform a wild-type plant. In addition, Edwards teaches that the AtHAP3b CAAT-box transcription factor appears to be expressed in relation to osmotic stress and hence, would have motivated one of ordinary skill in the art to produce a transgenic plant. Hence, it would have been obvious to produce a transgenic plant and select said plant based on a greater tolerance to osmotic stress. Given the success of Harada in making a transgenic plant overexpressing the LEC1 CCAAT-box transcription factor, one of ordinary skill in the art would have had a reasonable expectation of success.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

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F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a

terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1-3, 5, 10-13, 15 and 36 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 52 and 65 of copending Application No. 11/069,255. Although the conflicting claims are not identical, they are not patentably distinct from each other because they appear to encompass overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

14. No claims are allowed.

15. This Office action is non-final in view of the new grounds of rejection.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The central FAX number for official correspondence is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-1600.

/David H Kruse/
Primary Examiner, Art Unit 1638
11 April 2008

17. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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